



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

3/11/97
D1231B

PURGED

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

cc: HFI-35/FOI Staff
DWA

March 3, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN-36

Dennis Sokol
President
Sacred Heart Hospital
501 Summit Street
Yankton, South Dakota 57078

Dear Mr. Sokol:

On February 14, 1997, the Food and Drug Administration conducted an inspection of your Oxygen USP transfilling firm, RCS Home Medical Supply Center, 110 Eighth Avenue, Watertown, SD. The Investigator found your firm to be operating under significant deviations from Current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)].

Oxygen USP is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your medical gases are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of the product are not in conformance with 21 CFR 210 and 211. Violations encountered during the FDA inspection include, but are not limited to, the following:

1. Failure to assure that the purity of your Oxygen meets the monograph requirements of the United States Pharmacopeia.

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2. Failure to perform pre-fill leak and hammer tests.
3. Failure to establish a unique lot number for each manifold fill of medical cylinders.
4. Failure to document that each person engaged in the transfilling of medical gases has the education, training, and experience to enable that person to perform the assigned function.
5. Failure to perform required filter checks on the _____ Oxygen analyzer.
6. Failure to maintain separate or defined areas or other such control systems to prevent mix-up of empty, filled or quarantined cylinders.
7. Failure to have written procedures for the following:
 - A. Receipt, identification, storage, handling, sampling, examination and/or testing of labeling.
 - B. Establishing lot numbers or identifying the code.
 - C. Handling cylinders that have tested unacceptable.
 - D. Temperature checks and acceptable limits during transfilling operations.
 - E. Description of "pumpers lot" and instructions for completion and review.
 - F. Calibration of gauges.
 - G. Performance of pre- and post-fill cylinder leak testing.

You did not have a copy of the Operator's Manual for the _____ Oxygen Analyzer. The manual contains important information regarding the periodic maintenance, handling and other key facts to ensure that the analyzer is properly maintained and operated.

It was noted while reviewing the Investigator's report that you did not have a certified, high purity oxygen standard available to calibrate the _____ Oxygen Analyzer.

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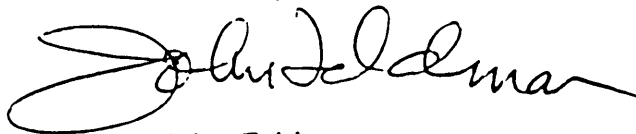
This letter is not meant to be all-inclusive. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Failure to do so may result in enforcement action without further notice. This includes seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you advise us in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within the requested time frame, you must promptly inform this office of the reason for the delay and the time when each violation will be corrected.

Your reply should be addressed to Rodney L. Bong, Acting Compliance Officer, at the address indicated on the letterhead.

Sincerely,

A handwritten signature in black ink, appearing to read "John Feldman", with a large, stylized initial "J" and a long, sweeping underline.

John Feldman
Director
Minneapolis District

RLB/ccl